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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,807

Applicant(s)

PATHAK, CHANDRASHEKHAR P.

Examiner

Abdel A. Mohamed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5,6,7,8.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT TO PRELIMINARY AMENDMENT, IDS AND STATUS OF THE CLAIMS

1. The preliminary amendment filed 2/5/02 and the information disclosure statement (IDS) and form PTO-1449 filed 6/6/02, 4/1/03, 6/9/03 and 7/21/03 are acknowledged, entered and considered. In view of Applicant's request claims 1-22 have been canceled and claims 23-48 have been added. Thus, claims 23-48 are now pending in the application.

OBJECTION TO TRADEMARKS AND THEIR USE

2. The use of the trademarks "Pluronic®", "Tetronic®", "Darocure 2959®", and "Pluronic F127®" have been noted in this application. The trademarks have not been capitalized, they should be capitalized wherever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner, which might adversely affect their validity as trademarks.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirements are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. § 112^{2nd} PARAGRAPH

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 40, 41, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40, 41, 47 and 48 are indefinite in the recitation "having a molecular weight from 600 to 10,000" (claims 40 and 47) and "having a molecular weight from 600 to 100,000" (claims 41 and 48) because the claims fail to identify whether the units of the molecular weights are in Daltons or kilo Daltons. Amendment of the claims to recite "having molecular weight from 600 to 10,000 Daltons" and "having molecular weight from 600 to 100,000 Daltons" as disclosed on pages 11, 16, 18, 35 and 36 in the instant specification is suggested.

CLAIM REJECTIONS-35 U.S.C. § 102(b)

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hubbell et al. (U.S. Patent No. 5,410,016).

The Hubbell et al. patent discloses biocompatible, biodegradable water soluble polymerizable crosslinking agent containing an inert polymeric component, a biodegradable component, and a protein reactive functional component. The water soluble polymeric crosslinking agent has a variety of uses *in vivo*. The polymeric crosslinking agent includes at least one water soluble region, at least one region which is biodegradable, usually by hydrolysis, and at least two free radical-polymerizable regions, wherein the water soluble region forms the central core of the polymeric crosslinking agent and has at least two degradable regions attached to the core. The '016 patent also discloses the polymeric crosslinking agent backbone is formed of a nondegradable backbone having water soluble regions as branches or grafts attached to the degradable backbone. Two or more polymerizable regions are attached to the water soluble branches or grafts. Thus, the crosslinking agent is linear and comprises a plurality of branches, wherein said plurality is greater than two and the inert component is flanked at each end with biodegradable component which is flanked at each end with a protein reactive functional component (See e.g., col. 4, lines 29 to col. 5, lines 14) as directed to claims 23-26, and as such the prior art anticipates the claims as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

Claims 23-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (U.S. Patent No. 5,410,016) taken with Rubinstein et al. (U.S. Patent No. 4,101,380) and Pathak et al. (U.S. Patent No. 6,156,531).

The Hubbell et al. patent as discussed above discloses biocompatible, biodegradable water soluble polymerizable crosslinking agent containing polymeric component, a biodegradable component, and a protein reactive functional component. The water soluble polymeric crosslinking agent has a variety of uses *in vivo*. The polymeric crosslinking agent includes at least one water soluble region, at least one region which is biodegradable, usually by hydrolysis, and at least two free radical-polymerizable regions, wherein the water soluble region forms the central core of the polymeric crosslinking agent and has at least two degradable regions attached to the core. The '016 patent also discloses the polymeric crosslinking agent backbone is formed of a nondegradable backbone having water soluble regions as branches or grafts attached to the degradable backbone. Two or more polymerizable regions are attached to the water soluble branches or grafts. Thus, the crosslinking agent is linear and comprises a plurality of branches, wherein said plurality is greater than two and the inert component is flanked at each end with biodegradable component which is flanked at each end with a protein reactive functional component (See e.g., col. 4, lines 29 to col. 5, lines 14) as directed to claims 23-26 and 28. Further, on cols. 5, 8, and Figure 1 and claims 1-14 and 19-23, the reference teaches the use of various components such

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as glycolide, lactide caprolactone, prolactone, poly(α -hydroxy acid), poly lactic acid, anhydrides, poly(ortoesters), poly(phosphoesters), polyanhydrides, polylactones, etc. The above biodegradable components are hydrolysable under *in vivo* conditions, and as such meet the limitations of claims 30-33, 36-38, 43 and 45. On col. 7, lines 61 to 65 and claim 1, the '016 patent discloses a biodegradable, polymerizable crosslinking agent having a solubility of at least about 1 g/100ml in an aqueous solution comprising at least one water soluble region, at least one degradable region which is hydrolysable under *in vivo* conditions as directed to claim 34. With respect to the molecular weights of the crosslinking agent, the '016 patent on col. 8, lines 12 to lines 27 states that the molecular weight of the crosslinking agent is between about 400 and 30,00 Daltons, which overlaps with the claimed molecular weights of 600 to 100,000, and as such meet the limitations of claims 40, 41, 47 and 48.

The reference of Hubbell et al. differs from claims 23-48 in not teaching the use of protein functional component such as hydroxysuccinimidyl ester and the functional groups capable of forming a covalent bond of said functional group, which consists of amine and thiol. However, Rubinstein et al. teach a process for cross linking of proteins, comprising reacting a protein with a crosslinking agent and include di-N-hydroxysuccinimidyl ester of poly(ethylene oxide) disuccinate, having molecular weight (See e.g., col. 2 and col. 8) as directed to claim 27. Further, the reference of Pathak et al. teaches method for crosslinking biological tissues, comprising reacting collagen with crosslinkers having functional groups, including isocyanate, epoxy and N-hydroxysuccinimide, or other collagen reactive functionalities known in the art, which can react with the side groups of collagen, including amine and thiol functionality (See e.g., col. 3, lines 5-37 and col. 5, lines 59 to col. 6, lines 3) as directed to claim 28.

In regard to claim 44 and 46, the claims are in product-by-process format and as such, it is the novelty and patentability of the instantly claimed product that need be established and not the recited process steps, *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976). Further, the prior art described the product as old, *In re Best*, 195 USPQ 430, 433 (CCPA 1977); (See MPEP 706.03[e]). Hence, the burden of proving that the process limitation makes a different product is shifted to the Applicant, *In re Fitzgerald*, 205 USPQ 594.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the method of the primary reference of '016 patent with the secondary references of '380 and '531 patents to prepare a water soluble polymeric cross linking agent comprising an inert water soluble polymeric component, biodegradable component, functional component reactive with chemical groups such as N-hydroxysuccinimide ester on a protein which provides for covalent bonding to proteins under *in vivo* conditions without free radical initiation. Thus, in view of the above and the combined teachings of the prior art, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRSPONDANCE

6 No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on (571) 272-0951. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications..

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Amr Mohamed/AAM

May 3, 2004